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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/152,698	09/02/1998	REGUPATHY MADIYALAKAN	A52023.1	4505

32254 7590 09/10/2002

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EXAMINER	
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ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/152,698	Madiyalakan et al
Examiner	**Art Unit**
Karen Can Ila	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *30, 61-63, 66, 67, 69, and 71-97* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *30, 61-63, 66, 67, 69, and 71-97* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. Claims 31 and 70 have been canceled. Claims 30, 61, 66, 67, 69 and 87 have been canceled. Claims 30, 61-63, 66, 67, 69 and 71-97 are pending and under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Withdrawn

3. The rejection of claims 30, 61, 62, 63, 71, 73, 74, 77, 78, 85, 86, 87, 91, 92, 94, 95 and 97 under 35 U.S.C. 102(b) as being anticipated by Morgan et al (US 4,879,225) is withdrawn in light of applicants argument.

4. The rejection of claims 61 and 62 under 35 U.S.C. 102(b) as being anticipated by Klaus (Nature, 1978, Vol. 272, pp. 265-266) is withdrawn in light of applicants amendment.

5. The rejection of claims 61-63, 77, 78, 79, 82-88, 91, 92, 93, 94, 95 and 96 under 35 U.S.C. 103(a) as being unpatentable over Madiyalakan et al (Hybridoma, 1994, Vol. 14, pp. 199-203, reference A2 of the IDS filed March 20, 2000) in view of Klaus (Nature, 1978, Vol. 272, pp. 265-266) is withdrawn in light of applicants amendment.

6. The rejection of claims 61, 63, 77, 78, 82, 83, 84, 85, 86, 87, 91, 92, 93, 94 and 96 under 35 U.S.C. 103(a) as being unpatentable over Fagerberg et al (Cancer Immunol Imunother, 1996, Vol. 42, pp. 81-87) or Frodin et al (Hybridoma, 1991, vol. 10, pp. 421-431) or Tsang et al (US 5,688,657) or Chu et al (US 5,652,114) in view of Klaus (Nature, 1978, Vol. 272, pp. 265-266) is withdrawn in light of applicants amendment.

7. The rejection of claims 66, 67 and 69 under 35 U.S.C. 103(a) as being unpatentable over Fagerberg et al (Cancer Immunol Imunother, 1996, Vol. 42, pp. 81-87) or Frodin et al (Hybridoma, 1991, vol. 10, pp. 421-431) or Tsang et al (US 5,688,657) or Chu et al (US 5,652,114) in view of Klaus (Nature, 1978, Vol. 272, pp. 265-266) as applied to the composition

claims 61, 63, 77, 78, 82, 83, 84, 85, 86, 87, 91, 92, 93, 94 and 96 above, and further in view of Tassi et al (Immunology Letters, 1991, Vol. 27, pp. 39-44) or Frodin et al (Hybridoma, 1991, Vol. 10, pp. 421-431) or Fagerberg et al (Cancer Immunol Immunother, 1996, Vol. 42, pp. 81-87) is withdrawn in light of applicants amendment.

8.

Claim Rejections Maintained

9. The rejection of claims 30, 67, 69, 71, and 73-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Koprowski et al (US 5,053,224) as evidenced by Chattopadhyay et al (Cancer Research, 1991, Vol.51, pp. 6045-6051) and Rooijen (Res Immunol, 1993, Vol. 144, pp. 545-552) is maintained for reasons of record. Claim 30 has been amended to specifically recite foreign binding agent. Claim 67 has been amended to specifically state that the binding agent is used to induce AB3 and AB3' in a patient, wherein the patient obtains a beneficial effect. Claim 69 has been amended to specify that non-radiolabeled monoclonal antibodies are administered to a patient and that anti-anti-idiotype antibodies are formed which react with the complexes formed between the monoclonal antibody and the antigen, wherein the production of said anti-anti-idiotype antibodies provide a beneficial effect to the patient. Applicant argues that Koprowski teaches the administration of anti-idiotype antibodies unlike the instant invention. This has been considered but not found persuasive. Claim 30 embodies a "foreign binding agent"; claim 67 embodies a method of using a "binding agent"; claim 69 embodies the administration of a "non-radiolabeled monoclonal antibody". The anti-idiotype antibody used by Koprowski is a binding agent and a monoclonal antibody. Amendment of the claims to recite Ab_1 in place of binding agent or "monoclonal antibody" would obviate this rejection.

10. The rejection of claims 66, 67 and 69 under 35 U.S.C. 102(e) as anticipated by Raso et al (US 6,140,091) is maintained for reasons of record. Claim 66 has been amended to specify that

the patient obtains beneficial effect. Claim 67 has been amended to specifically state that the binding agent is used to induce AB3 and AB3' in a patient, wherein the patient obtains a beneficial effect. Claim 69 has been amended to specify that non-radiolabeled monoclonal antibodies are administered to a patient and that anti-anti-idiotype antibodies are formed which react with the complexes formed between the monoclonal antibody and the antigen, wherein the production of said anti-anti-idiotype antibodies provide a beneficial effect to the patient. Applicant argues that Ab3' antibodies raised against cocaine-KLH would not be expected to provide a beneficial effect. This has been considered but not found persuasive. Raso et al discloses that treatments of with conventional or catalytic anti-cocaine antibodies has given encouraging results, therefore, it would be expected that administration of the antibodies disclosed by Raso would benefit a patient. Further, claims 67 and 69 do not specify that the beneficial effect to the patient must be through the generation of AB3': claim 67 reads on the induction of AB3 and AB3', wherein the patient obtains a beneficial effect and does not specify that said beneficial effect is due solely through the induction of AB3'. Claim 69 has been amended to read on the stimulation of anti-anti-idiotype antibodies that immunoreact with the complex formed between the monoclonal antibody and the antigen, wherein the production of anti-anti-idiotype antibodies provides beneficial effect to the patient. As such claim 69 does not exclude the production of anti-anti-idiotype antibodies which bind to antigen, as opposed to the antigen-antibody complex, as being produced by the administered non-radiolabeled monoclonal antibody.

11. The rejection of claim 69 under 35 U.S.C. 102(b) as being anticipated by Madiyalakan et al (Hybridoma, 1994, Vol. 14, pp. 199-203, reference A2 of the IDS filed March 20, 2000) as evidenced by either of Tassi et al (Immunology Letters, 1991, Vol. 27, pp. 39-44) or Frodin et al (Hybridoma, 1991, Vol. 10, pp. 421-431) or Fagerberg et al (Cancer Immunol Immunother, 1996, Vol. 42, pp. 81-87) is maintained for reasons of record. Claim 69 has been amended to

specify that the administered antibody is non-radioactive and that the anti-anti-idiotype antibodies include Ab3' antibodies. Applicant argues that neither of these limitations are taught by Madiyalakan. This has been considered but not found persuasive. Madiyalakan et al disclose the administration of a monoclonal antibody, Mab43.13, which induces the anti-anti-idiotypic antibodies in patients having circulating tumor antigen CA125 in the serum. Thus Madiyalakan et al disclose a method comprising the administration of a monoclonal antibody which binds to a soluble antigen in an amount sufficient to prolong the survival time in patients. Madiyalakan et al disclose that anti-idiotypic and anti-anti-idiotypic antibodies were generated in patients having circulating tumor antigen. Madiyalakan et al do not specifically disclose the specific nature of anti-anti-idiotype antibodies produced in terms of Ab3 or Ab3'. However it would be reasonable to assume that Ab3' was generated in addition to Ab3 as Rooijen discloses that antigenic determinants on anti-idiotypic antibodies which are not masked by association with Ab1 direct the activation of germinal centers and antibody production (page 548-549, under "Antiidiotypic antibodies and idiotypic networks in the follicles") and as Chattopadhyay et al disclose that anti-idiotypic antibodies mimic the original antigenic epitope in an imperfect way, and as such can activate B-cell clone able to bind to the self-tumor antigen, but which has not been deleted due to self-reactiveness (page 6050, first column, lines 30 to 35).

12. The rejection of claim 61 under 35 U.S.C. 102(e) as being anticipated by either Zanetti (US 5,583,202) is maintained for reasons of record. Applicant has amended claim 61 to delete the phrase "said modified antigen comprising an antigen bound by a binding agent". Claim 61 now reads "A composition for altering immunogenicity comprising a modified antigen bound to a binding agent. For the reasons set forth under the rejection under 112, second paragraph below, it is now unclear what constitutes a "modified" antigen. Applicant argues that Zanneti does not teach a modified antigen. This has been considered but not found persuasive. Zanetti discloses antigenized antibodies wherein epitopes of Plasmodium falciparum circumsporozoite protein

(CS) were inserted into the heavy chain of a mouse/human chimeric antibody. Thus the antigen is modified to the extent that it was incorporated into a heterologous protein context, and further, the antigen is now bound to a binding agent as the antigen is fused to the Fc portion of an antibody which can bind to Fc receptors.

13. The rejection of claims 30, 61-63, 66, 67, 69, 71, 73-80, 82-89, 91-97 under the judicially created doctrine of double patenting over claims 1-14 of U. S. Patent No. 6,241,985 is maintained for reasons of record.

14. The rejection of claims 72, 81 and 90 under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 6,086,873 is maintained for reasons of record.

15. Acknowledgment is made of applicant intent to file terminal disclaimers when the claims are found allowable.

16. The declaration, filed January 7, 2002, remains defective. Point 5 of the "remarks" states "an executed declaration is enclosed". However, the declaration was not enclosed with the amendment filed June 10, 2002, nor in the subsequent copy transmitted by Fax.

New Grounds of Rejection

17. Claims 61-63 and 77-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 has been amended to recite : A composition....comprising a modified antigen bound to a foreign binding agent, which is in contrast to the previous version of the claim reciting: A composition...comprising a modified antigen, said modified antigen comprising an antigen bound to a binding agent. Without the definition of modified antigen that was set forth in the originally filed claim, the specification lack a definition of what constitutes the currently claimed "modified" antigen. Therefore the metes and bounds of claim 61 cannot be determined.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Patent Examiner, Group 1642
September 9, 2002

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